



LETTER OF ANNOUNCEMENT Batch recall guidance

17th October 2019

Dear all,

EMVO has been informed about a large number of alerts currently being caused due to incorrect actions in the event of a batch recall.

According to Article 40 (c) of the <u>Delegated Regulation (EU) 2016/161</u>, a batch recall must be reflected within the EMVS. (EU Hub and National Systems)

When recalling a batch, the OBP needs to make reference to the Product Code, the Batch ID, the reason for recall and state the list of affected markets. The EU Hub will then inform the affected markets of the batch recall requirement.

It is vital that batch recalling should only be performed only **once** and not multiple times on the same batch.

Once a batch recall has been implemented, no further actions should be performed on the packs affected by the batch recall. Do not subsequently attempt to alter the pack status, for example to 'Destroyed'. When a batch is recalled, all other pack status change use cases must not be carried out.

A batch recall within the EMVS is an irreversible action.

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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EMVO Team

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